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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,175	09/15/2003	Dean A. Smith	COL-014	9441

7590 10/31/2005

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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,175	Applicant(s) SMITH ET AL.	
	Examiner Traviss C. McIntosh	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase "with the proviso that R^1, R^2, R^3. and R^4 are not all H" which is on the top line of page 32 has a period between the R^3 and the R^4 moieties, wherein the period should be a comma. Appropriate correction is required.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with information which is not clear, concise and exact. Examples of some unclear, inexact or verbose information used in the specification are: the table on page 19 indicates the alkyl and OH values for compounds from examples 2-9, however, only compounds 1-8 were made with this method; applicants methods on page 20 use a reactant with R", which is not defined in the disclosure; the results on page 27 indicate that "application example 1 demonstrated exceptional antimicrobial activity against all four test organisms...", however, it is noted that application example 1 had no activity on 1 of the 4 test organisms, and only had very slight activity against another of the test organisms in 1 concentration tested. Moreover, it is noted that the examiner has not been able to determine exactly what compounds were tested. It appears that applicants made 8 glycoside compounds (examples 1-8) and then made 6 reactants (examples 9-14) and subsequently reacted various compounds from examples 1-8 with the reactants of examples 9-14 to provide final products 15-

26, however, the examiner has not been able to determine as to exactly what compounds were tested. The specification should be revised in it's entirety carefully in order to comply with 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting certain microbial growth with certain compounds, does not reasonably provide enablement for inhibiting microbial growth from bacteria, fungi, yeasts, and mold, by using the broad composition as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in ***In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)***. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;

(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims - The nature of the invention

Claim 1 is drawn to a method for inhibiting microbial growth by contacting a substrate subject to attack by microorganisms selected from the group consisting of bacteria, fungi, yeasts, and mold, with a composition which conforms to the structures of (a) and (b) (alkyl glycosides), as set forth in the claims. Claims 2-7 limit the length of the alkyl chain of R^{12}.

The state of the prior art

Alkyl glycosides are known in the art to be used as surfactants, as seen by Urfer et al. (US Patent 3,087,320). Moreover, antimicrobial agents are known to be diverse in structure and function, such as the octoxyglycerine compositions of Modak et al. (US Patent 6,846,846), the compounds, including triclosan, of Levy et al. (US 2004/0024068), and the compounds of Payne et al. (US 2003/0026833).

The level of predictability in the art

The examiner acknowledges the probability and predictability that certain compositions as disclosed by applicant indeed have efficacy against certain microbes, however the art is silent with regard to the predictability of any of the instant compositions to have efficacy against any bacteria, fungi, yeast, or mold.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the scope of claim as written. The examiner notes, there has not been provided sufficient instruction or sufficient methodological procedures to support the alleged efficacy instantly asserted using a compound from the broad group of claim 1.

The existence of working examples

The working examples in the instant application are drawn to the following:

Examples 1-8 are drawn to methods of introducing alkanols onto what appears to be the compounds of formula (a) of claim 1 (as by the use of only dextrose). It is noted that the examiner is confused as to way example 9 is listed in the table on page 19, as this example is seen to be made by the following reaction, and not this reaction.

Examples 9-14 are drawn to methods of functionalizing various hydroxyl groups.

Examples 15-26 are drawn to methods of reacting the alkyl glycosides of examples 1-6 with the epoxy reactants of examples 9-14.

The microbial activity was then tested for 3 compounds from example 18, 23, and 22 for activity against 4 microbes, S. aureus (bacteria), P. aeruginosa (bacteria), C. albicans (yeast) and A. niger (mold). It is noted that the results of these tests indicate that not all of the compounds tested are effective against all the microbes. For example, application example 1 was not effective against P. aeruginosa at any concentration tested, and was only slightly effective against A. niger in 1 of the 3 concentrations tested. Additionally, application example 2 was not effective against A. niger, and was not effective against C. albicans in 1 of the concentrations tested, was slightly

effective in another concentration, and had good activity in a third concentration tested. As such, it is found that there has not been provided sufficient evidence which would warrant the skilled artisan to accept the data and information provided in the working examples as correlative proof that any compound of claim 1 would indeed provide microbial activity against any of the pathogens as claimed.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the use of any composition of claim 1 without undue experimentation. One skilled in the art could not use the entire scope of the claimed invention without undue experimentation. One skilled in the art would be confronted with an undue burden of experimentation to prepare, characterize, and test the various compounds of claim 1 against various pathogens to determine if indeed they have efficacy as instantly asserted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in the fact that the claim is drawn to a method of inhibiting microbial growth comprising contacting a substrate with an antimicrobial composition

"conforming to the following structure:", and then the claim lists structure (a) **and** (b). How can a composition conform to a structure of 2 divergent molecules? Does applicant intend the composition to be a combination of the 2 agents, or to comprise only one or the other of the two agents? Moreover, it is noted that if applicants intend the composition to only include 1 of the 2 agents, then it is unclear how the claim can comprise a composition, as it would only contain 1 item, and that is a compound, not a composition. Upon review of the specification, the examiner has been unable to determine exactly what compounds are being administered.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
October 13, 2005

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623